WIMMER SYSTEMS
INNOVATIVE SOFTWARE SOLUTIONS

COMPANY   SERVICES   PRODUCTS   PORTFOLIO   CONTACT

Wimmer Systems, LLC. provides innovative software solutions to FDA/EPA regulated industries. Our Data Compliance System™ for Microsoft Excel®provides your company with a 21 CFR Part 11 compliant solution to data processing. We also develop and host database-driven web sites, using some of the most powerful technologies available. Whether you need a laboratory compliance solution or to get your mission-critical data on the web, Wimmer Systems can provide you with a compliant, validated system. Click on the categories above for more information.

NOW AVAILABLE

A demo version of DCS for Windows, Excel 97/2000 is available.

Please follow the instructions to get a copy.

Visit us at the following conferences for live product demonstrations:

December 4-5 PDA Annual Meeting, Philadelphia PA -- Booth #512
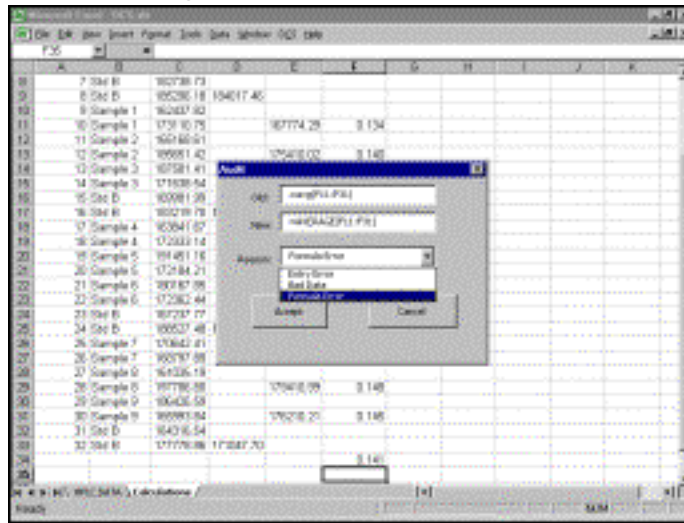
Data Compliance System™
for Microsoft Excel®

Wimmer Systems has developed the Data Compliance System™ for Microsoft Excel®. DCS was created to solve the need for an easy-to-use data processing system compliant with 21 CFR Part 11 requirements. DCS provides ease of use, flexibility, security, and traceability in a simple, cost-effective solution to Part 11 compliance.

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Data Compliance System™
for Microsoft Excel®

Ease of Use

* DCS itself is an Excel workbook, making system administration a breeze. No permanent changes are made to Excel, and DCS can be loaded on demand.

* Users can work in Excel without restriction, with DCS monitoring for changes to the data.

* The user is only interrupted when real changes are made to data. Original entries are recorded in a silent audit trail, and formatting changes (such as alignment or font) are ignored. Click on the image below to see the audit trail being activated.

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Here the user changed the formula in cell F34. After hitting the enter key to commit the change (and moving the selection to F35) the audit trail was activated.

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Flexibility

*   DCS saves files as standard Excel workbooks. Any person with Excel can open the workbook or import data from it, but cannot make changes to the workbook without using DCS.
*   Workbook data can be imported into or linked to Word documents while retaining data security and authenticity.
*   Send workbooks to other users, departments, clients, even the FDA, knowing your data is secure, traceable, and authentic. Your workbook can only be changed by authorized users, and all changes are tracked.
*   DCS works with any system with Export to Excel or Import from Excel functions, making it the perfect choice for secure transfer of data to and from your existing LIMS or CDS.
*   DCS can be configured to run over your network or on stand-alone PCs.

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Security

* Fully compliant with 21 CFR Part 11 requirements for system and user security.
* Security options can be set by the system administrator to follow your corporate security policies.
* DCS can be customized to integrate with your existing LIMS/CDS security protocols for seamless operation.
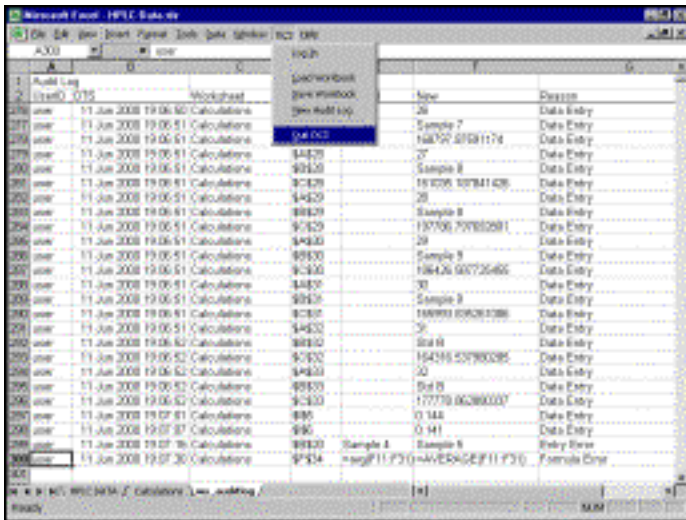* There are several options available for security databases.

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Traceability

* The customizable audit trail captures such information as the user identification, date/time stamp, location of data in the workbook (worksheet name, cell), original value, new value, and the reason for making the change.
* The audit trail captures changes to both data and formulas, as shown in the screen shot below. (Click to enlarge.)
* The reason for change may be picked from a list of pre-defined reasons or the user may type in a new reason.
* The audit trail function can be customized to generate silent audit trails for automated processes, such as recalculation by macros.
* Audit trails are bound to the data. The audit trail is kept in the same workbook as the data, and DCS prevents users from making changes to the audit trail.

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	A	B	C		E	F	G
1	Audit Log						
2	UserID	DTS	Worksheet			New	Reason
276	user	11 Jun 2000 19:06:50	Calculations			26	Data Entry
277	user	11 Jun 2000 19:06:51	Calculations			Sample 7	Data Entry
278	user	11 Jun 2000 19:06:51	Calculations			168797.87591174	Data Entry
279	user	11 Jun 2000 19:06:51	Calculations	A28		27	Data Entry
280	user	11 Jun 2000 19:06:51	Calculations	B28		Sample 8	Data Entry
281	user	11 Jun 2000 19:06:51	Calculations	C28		161035.187841426	Data Entry
282	user	11 Jun 2000 19:06:51	Calculations	A29		28	Data Entry
283	user	11 Jun 2000 19:06:51	Calculations	B29		Sample 8	Data Entry
284	user	11 Jun 2000 19:06:51	Calculations	C29		197786.797692801	Data Entry
285	user	11 Jun 2000 19:06:51	Calculations	A30		29	Data Entry
286	user	11 Jun 2000 19:06:51	Calculations	B30		Sample 9	Data Entry
287	user	11 Jun 2000 19:06:51	Calculations	C30		186426.587725455	Data Entry
288	user	11 Jun 2000 19:06:51	Calculations	A31		30	Data Entry
289	user	11 Jun 2000 19:06:51	Calculations	B31		Sample 9	Data Entry
290	user	11 Jun 2000 19:06:51	Calculations	C31		165993.835261086	Data Entry
291	user	11 Jun 2000 19:06:51	Calculations	A32		31	Data Entry
292	user	11 Jun 2000 19:06:52	Calculations	B32		Std B	Data Entry
293	user	11 Jun 2000 19:06:52	Calculations	C32		164316.537980285	Data Entry
294	user	11 Jun 2000 19:06:52	Calculations	A33		32	Data Entry
295	user	11 Jun 2000 19:06:52	Calculations	B33		Std B	Data Entry
296	user	11 Jun 2000 19:06:52	Calculations	C33		177778.862880337	Data Entry
297	user	11 Jun 2000 19:07:01	Calculations	I5		0.144	Data Entry
298	user	11 Jun 2000 19:07:07	Calculations	I6		0.141	Data Entry
299	user	11 Jun 2000 19:07:16	Calculations	B20	Sample 4	Sample 5	Entry Error
300	user	11 Jun 2000 19:07:30	Calculations	F34	=avg(F11:F31)	=AVERAGE(F11:F31)	Formula Error
301							

HPLC DATA / Calculations \ ws_auditlog /

Of course, the userID of "user" seen above would be replaced with the actual user's identification, linked in the workbook to their full name and other identifying characteristics, such as organization and location.

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DCS can be used for
* Data Entry Templates
* Data Reprocessing
* Sequence File Maintenance
* Secure Data Transfer
* Electronic Submissions
* And More!

Customize DCS...
* ...to integrate with your existing computer systems.
* ...by adding custom functions or your existing Excel modules.
* ...to function according to your company's SOPs.

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Demonstration Version
Please click here to request the demo of DCS for Windows.

System Requirements
Microsoft Excel 97 or 2000
Windows or Macintosh

Configuration
Network or Stand-Alone

Pricing
Licensing options are available to suit your needs and budget. Please contact us for details.

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